

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q86915

Yoshiaki ISOBE, et al.

Appln. No.: 10/528,373

Group Art Unit: Unknown

Confirmation No.: Unknown

Examiner: Unknown

Filed: March 18, 2005

For: NOVEL URACIL DERIVATIVES AND MEDICINAL USE THEREOF

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

1. Japanese Laid-Open Patent Publication No. 08-27121 published January 30, 1986, to Japan Enajii Kk, with English Abstract. This reference was previously listed on a PTO/SB/08 A & B filed with the application on March 18, 2005. For the Examiner's convenience, a copy is enclosed herewith.
2. M. Tobe et al., "Synthesis and Biological Evaluation of CX-659S and its Related Compounds for their Inhibitory Effects on the Delayed-Type Hypersensitivity Reaction", *Bioorganic & Medicinal Chemistry*, Vol. 8, 2000, pp. 2037-2047. This reference was previously listed on a PTO/SB/08 A & B filed with the application on March 18, 2005. For the Examiner's convenience, a copy is enclosed herewith.
3. M. Mizoguchi et al., "Cyclosporin ointment for psoriasis and atopic dermatitis", *The Lancet*, Vol. 339, May 5, 1992, pp. 1120.

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4. J.G. Meingassner et al., "Immunosuppressive Macrolides of the Type FK 506: A Novel Class of Topical Agents for Treatment of Skin Diseases?", *The Journal of Investigative Dermatology*, Vol. 98, No. 6, June 1992, pp. 851-855.
5. U.S. Patent No. 5,661,153 issued August 26, 1997, to Isobe et al. This patent corresponds to JP-A 08-109171 A, which is referred to in the present specification at page 2, line 19.
6. U.S. Patent No. 5,821,247 issued October 13, 1998, to Isobe et al. This patent corresponds to JP 3093170, which is referred to in the present specification at page 2, line 20.
7. U.S. Patent No. 5,877,138 issued March 2, 1999, to Isobe et al. This patent also corresponds to JP 3093170, which is referred to in the present specification at page 2, line 20.
8. J.-L. Bernier et al., "Substitutions en 5 sur le diméthyl-1,3 amino-4 uracile", *Bulletin de la Société Chimique de France*, No. 3-4, 1976, pp. 616-620, with English Abstract.
9. S. Senda et al., "Pyrimidine Derivatives and Related Compounds. XIX. Synthesis and Analgetic and Antiinflammatory Activities of 1,3-Substituted 5-Dimethylaminouracil Derivatives", *Chem. Pharm. Bull.*, Vol. 22, No. 1, 1974, pp. 189-195.
10. J. Lars et al., "The Directing Effect of Annelated Rings in Aromatic Systems—II Synthesis and Oxidation of 2,3-Dihydro-5-Benzo-Furanols—I. An Apparent Mills-Nixon Effect in Oxidative Coupling of Phenols", *Tetrahedron*, Vol. 26, 1970, pp. 879-886.
11. U.S. Patent No. 5,719,180 issued February 17, 1998, to Shudo et al. This patent corresponds to JP-A 07-215959 A, which is referred to in the present specification at page 40, line 20.
12. W.T. Caldwell et al., "Nuclear Methylation of Phenols. A New Synthesis of Intermediates in the Preparation of Antisterility Factors", *Journal of American Chemical Society*, Vol. 61, April 1939, pp. 765-767.
13. G.L. Asherson et al., "Contact and Delayed Hypersensitivity in the Mouse", *Immunology*, Vol. 15, 1968, pp. 405-416.
14. D. Tobin et al., "Increased number of immunoreactive nerve fibers in atopic dermatitis", *J. Allergy Clin. Immunol.*, Vol. 90, No. 4, Part 1, October 1992, pp. 613-622.

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15. A. Giannetti et al., "Skin reactivity to neuropeptides in atopic dermatitis", *British Journal of Dermatology*, Vol. 121, 1989, pp. 681-688.
16. Y. Kuraishi et al., "Scratching behavior induced by pruritogenic but not algesiogenic agents in mice", *European Journal of Pharmacology*, Vol. 275, 1995, pp. 229-233.
17. N. Inagaki et al., "Evaluation of anti-scratch properties of oxatamide and epinastine in mice", *European Journal of Pharmacology*, Vol. 400, 2000, pp. 73-79.
18. H. Kohn et al., "Preparation and Anticonvulsant Activity of a Series of Functionalized  $\alpha$ -Aromatic and  $\alpha$ -Heteroaromatic Amino Acids", *J. Med. Chem.*, Vol. 33, 1990, pp. 919-926.
19. N. Sugiyama et al., "Synthesis and Topical Antiinflammatory and Antiallergic Activities of Antioxidant o-Aminophenol Derivatives", *J. Med. Chem.*, Vol. 37, 1994, pp. 1977-1982.
20. K. Kuriyama et al., "Vitamin E ointment at high dose levels suppresses contact dermatitis in rats by stabilizing keratinocytes", *Inflammation Research*, Vol. 51, 2002, pp. 483-489.
21. Japanese Laid-Open Patent Publication No. 2003-212872 published July 30, 2003, to Japan Energy Corp., with English Abstract.

One copy of each of the listed documents is submitted herewith, except for the U.S. patents.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.


The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

  
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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: April 27, 2005

Substitute for Form 1449 A & B/PTO  <b><u>INFORMATION DISCLOSURE</u></b> <b><u>STATEMENT BY APPLICANT</u></b>  (use as many sheets as necessary)				<b>Complete if Known</b> Application Number      10/528,373 Confirmation Number      Unknown Filing Date      March 18, 2005 First Named Inventor      Yoshiaki ISOBE Art Unit      Unknown Examiner Name      Unknown Attorney Docket Number      Q86915			
Sheet	1	of	1				
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
		Number	Kind Code <sup>2</sup> (if known)				
		US 5,661,153	A	08-26-1997	Isobe et al.		
		US 5,821,247	A	10-13-1998	Isobe et al.		
		US 5,877,318	A	03-02-1999	Isobe et al.		
		US 5,719,180	A	02-17-1998	Shudo et al.		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		JP	2003-212872	A	07-30-2003	Japan Energy Corp.	Abstract
<b>NON PATENT LITERATURE DOCUMENTS</b>							
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.					Translation <sup>6</sup>
		M. Mizoguchi et al., "Cyclosporin ointment for psoriasis and atopic dermatitis", <i>The Lancet</i> , Vol. 339, May 5, 1992, pp. 1120					
		J.G. Meingassner et al., "Immunosuppressive Macrolides of the Type FK 506: A Novel Class of Topical Agents for Treatment of Skin Diseases?", <i>The Journal of Investigative Dermatology</i> , Vol. 98, No. 6, June 1992, pp. 851-855					
		J.-L. Bernier et al., "Substitutions en 5 sur le diméthyl-1,3 amino-4 uracile", <i>Bulletin de la Société Chimique de France</i> , No. 3-4, 1976, pp. 616-620, with English Abstract					
		S. Senda et al., "Pyrimidine Derivatives and Related Compounds. XIX. Synthesis and Analgetic and Antiinflammatory Activities of 1,3-Substituted 5-Dimethylaminouracil Derivatives", <i>Chem. Pharm. Bull.</i> , Vol. 22, No. 1, 1974, pp. 189-195					
		J. Lars et al., "The Directing Effect of Annelated Rings in Aromatic Systems—II Synthesis and Oxidation of 2,3-Dihydro-5-Benzo-Furanols—I. An Apparent Mills-Nixon Effect in Oxidative Coupling of Phenols", <i>Tetrahedron</i> , Vol. 26, 1970, pp. 879-886					
		W.T. Caldwell et al., "Nuclear Methylation of Phenols. A New Synthesis of Intermediates in the Preparation of Antisterility Factors", <i>Journal of American Chemical Society</i> , Vol. 61, April 1939, pp. 765-767					
		G.L. Asherson et al., "Contact and Delayed Hypersensitivity in the Mouse", <i>Immunology</i> , Vol. 15, 1968, pp. 405-416					
		D. Tobin et al., "Increased number of immunoreactive nerve fibers in atopic dermatitis", <i>J. Allergy Clin. Immunol.</i> , Vol. 90, No. 4, Part 1, October 1992, pp. 613-622					
		A. Giannetti et al., "Skin reactivity to neuropeptides in atopic dermatitis", <i>British Journal of Dermatology</i> , Vol. 121, 1989, pp. 681-688					
		Y. Kuraishi et al., "Scratching behavior induced by pruritogenic but not algesciogenic agents in mice", <i>European Journal of Pharmacology</i> , Vol. 275, 1995, pp. 229-233					
		N. Inagaki et al., "Evaluation of anti-scratch properties of oxatomide and epinastine in mice", <i>European Journal of Pharmacology</i> , Vol. 400, 2000, pp. 73-79					
		H. Kohn et al., "Preparation and Anticonvulsant Activity of a Series of Functionalized $\alpha$ -Aromatic and $\alpha$ -Heteroaromatic Amino Acids", <i>J. Med. Chem.</i> , Vol. 33, 1990, pp. 919-926					
		N. Sugiyama et al., "Synthesis and Topical Antiinflammatory and Antiallergic Activities of Antioxidant o-Aminophenol Derivatives", <i>J. Med. Chem.</i> , Vol. 37, 1994, pp. 1977-1982					
		K. Kuriyama et al., "Vitamin E ointment at high dose levels suppresses contact dermatitis in rats by stabilizing keratinocytes", <i>Inflammation Research</i> , Vol. 51, 2002, pp. 483-489					
Examiner Signature					Date Considered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached